DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN - 7 2002

NADA 034-254
NADA 039-402
NADA 140-338

Thomas R. Schriemer, Director
Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer,

We refer to your Drug Experience Report dated August 6, 2001 for Naxcel (ceftiofur sodium) Sterile Powder, NADA 140-338, that refers to several other regulated products including MGA® (melengestrol acetate) 100/200 premix, NADA 034-254, MGA® (melengestrol acetate) 500 premix, NADA 039-402. The submission includes a 124-page reproduction of your firm's website. We note unapproved claims made for MGA® on pages 19 and 33 of the reproduction that violate the Federal Food, Drug, and Cosmetic Act (FFDCA) and applicable regulations.

The products chart entitled *"US Beef Product Information"* on page 19 and on your current web site (*http://durablecure.com/products.asp?country=US&Lang=EN&id=FAQ&tab=1*), under column entitled *"Approved Uses"*, includes *"estrus synchronization"* in addition to other approved claims. Also, the paragraph entitled *"Makes It Profitable to Feed Heifers"* on page 33, and on your current website (*http://durablecure.com/minor_product_overview.asp?drug=MG&country=US&lang=EN&species=BF*) states *"whether you use* [MGA] *as a heifer management tool or a breeding synchronization tool..."*. This claim is not approved and is, therefore, misleading. We are not aware of adequate and well-controlled studies demonstrating efficacy of this product for estrus synchronization.

The approved claims for use of your product in heifers are **"for increase in rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses" (or "reduction of liver condemnation due to liver abscesses")**. Only these benefits are acceptable for use in promotional and advertising materials regarding use of the product in cattle.

Unapproved claims, recommendations, or suggestions in labeling causes your product to be misbranded under the FFDCA. We request you to immediately revise your website with the correct information and refrain from using this unsubstantiated claim in all of your future promotional materials. We remind you of the commitment you made when you signed the new animal drug application (NADA) form FDA-356 that labeling and advertising would prescribe, recommend, or suggest product usage only in accord with labeling provided for in the approved application.

If you wish to submit a supplemental NADA in support of these new claims, please contact the Office of New Animal Drug Evaluation. We expect to receive your response within 30 days of receipt of this letter. If you have any questions you may contact us at (301)827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine.